

AMENDMENT TO THE CLAIMS

1-83. (Cancelled)

84. (New) A method for validating a treatment process for reducing the amount or activity of a contaminating biological agent in a sample, comprising:

exposing an indicator and the contaminating biological agent to the treatment process,

wherein the indicator is a thermostable kinase,

the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides, and prions, and

the treatment process comprises an exposure to at least one member selected from the group consisting of pH, temperature, pressure, enzyme, detergent, chemical sterilant, and gas-phase sterilant.

85. (New) The method of claim 84, wherein the thermostable kinase is immobilised as part of a solid support.

86. (New) The method of claim 84, wherein the thermostable kinase comprises adenylate kinase, acetate kinase, or pyruvate kinase.

87. (New) The method of claim 85, wherein the solid support comprises an indicator strip, a dip stick, or a bead.

88. (New) The method of claim 84, wherein the contaminating biological agent comprises a transmissible spongiform encephalopathy.

89. (New) The method of claim 84, wherein the thermostable kinase has an amino acid sequence selected from the group consisting of SEQ ID Nos: 1-25.

90. (New) The method of claim 84, wherein the thermostable kinase is encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos: 26-30.

91. (New) A biological process indicator for validating a treatment process for reducing the amount or activity of a contaminating biological agent in a sample,

comprising a thermostable kinase that retains at least 95% activity after exposure to 70° C for 30 minutes,

wherein validating the treatment process comprises exposing the thermostable kinase and the contaminating biological agent to the treatment process,

the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides, and prions,

the treatment process comprises an exposure to at least one member selected from the group consisting of pH, temperature, pressure, enzyme, detergent, chemical sterilant, and gas-phase sterilant, and

the thermostable kinase is immobilised as part of a solid support.

92. (New) The biological process indicator of claim 91, wherein the thermostable kinase comprises adenylate kinase, acetate kinase, or pyruvate kinase.

93. (New) The biological process indicator of claim 91, wherein thermostable kinase has an amino acid sequence selected from the group consisting of SEQ ID Nos:1-25.

94. (New) The biological process indicator of claim 91, wherein thermostable kinase is encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos:26-30.

95. (New) The biological process indicator of claim 91, wherein the solid support comprises an indicator strip, a dip stick, or a bead.

96. (New) A kit for validating a treatment process for reducing the amount or activity of a contaminating biological agent in a sample comprising:

a biological process indicator of claim 91, and
a substrate for the biological process indicator.

97. (New) A method for validating a treatment process, comprising:
obtaining a sample that may contain a contaminating biological agent;

exposing a mixture comprising the sample and a defined amount of a thermostable kinase to the treatment process, wherein the treatment process reduces an amount or activity of the contaminating biological agent;

measuring a residual kinase activity and optionally calculating a reduction in kinase activity; and

comparing said residual activity to a predetermined kinase activity, or comparing said reduction in kinase activity to a predetermined reduction in kinase activity, wherein the predetermined kinase activity or predetermined reduction in kinase activity corresponds to a confirmed reduction in the amount or activity of the contaminating biological agent under identical treatment process conditions,

wherein the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides, and prions, and

the treatment process comprises an exposure to at least one member selected from the group consisting of pH, temperature, pressure, enzyme, detergent, chemical sterilant, and gas-phase sterilant.

98. (New) The method of claim 97, wherein the infectious biological agent comprises a transmissible spongiform encephalopathy.

99. (New) The method of claim 97, wherein the thermostable kinase comprises an adenylate kinase, an acetate kinase, or a pyruvate kinase.

100. (New) The method of claim 97, wherein the thermostable kinase has an amino acid sequence selected from the group consisting of SEQ ID Nos:1-25.

101. (New) The method of claim 97, wherein the thermostable kinase is encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos:26-30.

102. (New) A method of correlating the reduction in the amount or activity of a contaminating biological agent in a sample with the thermostable kinase activity of the biological process indicator according to claim 91, comprising:

(i) preparing a first sample comprising a defined amount of the contaminating biological agent and a second sample comprising a defined amount of the thermostable kinase;

(ii) subjecting the first and second samples to a treatment process comprising an exposure to at least one member selected from the group consisting of pH, temperature, pressure, enzyme, detergent, chemical sterilant, and gas-phase sterilant;

(iii) measuring the residual activity of the kinase and optionally calculating the reduction in kinase activity;

(iv) measuring residual amount or activity of the contaminating biological agent and optionally calculating the reduction in the amount or activity of the contaminating biological agent; and

(v) repeating steps (i) to (iv), wherein at least one parameter of the treatment process is changed,

wherein the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides, and prions.

103. (New) The method of claim 102, wherein the contaminating biological agent comprises a transmissible spongiform encephalopathy.